



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------|---------------------|------------------|
| 09/525,797 | 03/15/2000 | Athanasius A Anagnostou | 5218-39B | 9917 |
| 20792 | 7590 | 09/06/2006 | | EXAMINER |
| MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627 | | | | UNGAR, SUSAN NMN |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/525,797 | ANAGNOSTOU ET AL. | |
| | Examiner | Art Unit | |
| | Susan Ungar | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 June 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 12, 15, 19-21, 24-26 and 31-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 12, 15, 19-21, 24-26, 31-35 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

Art Unit: 1642

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2006 are acknowledged and have been entered. Claims 1-11, 13-14, 16-18, 22-23, 27-30 are canceled and claims 12, 15, 19, 21, 24, 26, 34 have been amended. An action on the RCE follows.

2. Claims 12, 15, 19-21, 24-26, 31-35 are pending and currently under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following rejections are being maintained:

Claim Rejections - 35 USC 112

5. Claims 12, 31-35 remains rejected under 35 USC 112 and claims 15, 19-20 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed January 27, 2006, Section 6, pages 5-7.

Applicant argues that the Sigounas Declaration shows that EPO can modulate tumor responses to chemotherapy other than CIS or CIS derivatives wherein a notable reduction in tumor response was shown in the experiments to MTX. Further, Applicant argues that statistically significant data is not required in order to enable an invention and that the Signournas Declaration meets the requirement for data, that is that it provides a reasonable indication of a reduction in tumor mass as a result of sequential administration of EPO and mitomycin. The argument has been considered but has not been found persuasive because no

reduction of tumor response was shown in the experiments to MTX. Further, as drawn to the broad claims 12, 31-35, 19-20, the arguments are not found persuasive for the reasons of record because the claims are not limited to CIS, CIS derivatives or mitomycin.

Specifically as drawn to the Signournas Declaration, as previously set forth, although the Declaration is drawn to assay of not only CIS and CIS derivatives but also to MITO and CTX, no information is presented in the Declaration drawn to either MITO or CTX, thus it can only be assumed that results were not reported because the assay demonstrated that the claimed invention, that is administration of EPO prior to administrative of MITO or CTX was not differentially effective in producing a tumor reduction compared to MITO or CTX alone. Further, although Applicant opines, on page 7 of the response filed 11/2/05, that “Sequential administration of EPO and mitomycin C (MITO) showed a reduction in tumor mass compared to the reduction observed with MITO alone,” which was not significant”, this information cannot be evaluated since no objective evidence drawn to MITO is presented.

New Grounds of Rejection

Claim Rejections - 35 USC 112

6. Claims 12, 15, 19-21, 24-26, 31-35 are rejected under are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of administering EPO prior to initial administration of chemotherapeutic has no clear support in the specification and the claims as originally filed. In the paper submitted June 27, 2006, Applicant argues that support for the amendment of the claims to recite that EPO is administered “prior to initial administration of chemotherapeutic” can be found in

the specification and drawings as originally filed and that upon a fair reading of the specification one of ordinary skill would recognize that the timing of the EPO administration “prior to” conveys administration prior to the initiation of the first dose of chemotherapy and Applicant points specifically to *in vitro* cell culture studies where EPO was added to the culture medium prior to chemotherapeutic. The argument has been considered but has not been found persuasive because the *in vitro* data is not commensurate in scope with the claimed invention. Applicant further argues that the Sigounas Declaration provides *in vivo* data that supports the administration of EPO prior to administration of chemotherapeutic. The argument has been considered but has not been found persuasive because the information in the Sigounas Declaration is not found in the specification as originally filed and support for any amendment must be found therein.

Further, a review of the specification reveals that the term “prior” appears, in conjunction with suppression of endothelial growth five times. In particular, at page 3, lines 17-19 the specification states “The endothelial-inhibiting amount of erythropoietin may be administered simultaneously with, prior to, or after the chemotherapeutic agent.” At page 3, lines 24-26 the specification states that “The endothelial-inhibiting amount of erythropoietin may be administered simultaneously with, prior to, or after the chemotherapeutic agent.” At the paragraph bridging pages 10-11 “The two compounds may be administered simultaneously (concurrently) or sequentially. Finally the term “prior” is used twice at pages 17-18 wherein the specification describes an *in vitro* assay which as set forth above is an experiment that is not commensurate in scope with the claimed invention.”

Thus, it is clear that the specifically claimed limitation of "prior to initial" was in fact not specifically contemplated and that the limitation of the claims to "prior to initial" appears to exclude administration of EPO during the course of chemotherapy which is clearly not contemplated by the specification as originally filed. The subject matter claimed in claims 12, 15, 19-21, 24-26, 31-35 broadens the scope of the invention as originally disclosed in the specification.

7. No claims allowed.
8. All other objections and rejections previously set forth are hereby withdrawn.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this

application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
August 29, 2006

A handwritten signature in black ink, appearing to read "Susan Ungar".